

Site Amendment - Completing & Submitting

Site Amendments in REGIS

The following Site Amendment types can be submitted via REGIS;

- ❖ **Addition of a Site** update the study details of the additional site(s) and investigator(s). NSW sites will have a site application form generated in REGIS. *If Ethics is in REGIS, do not create this amendment.*
- ❖ **Change to CPI** notify the RGO of changes to the Coordinating Principal Investigator. *If Ethics is in REGIS, do not create this amendment.*
- ❖ **Change to PI** notify the RGO of changes to the Site Principal Investigator. *If Ethics is in REGIS, do not create this amendment.*
- ❖ **Request for an extension of HREC Approval** notify the RGO that the HREC has extended the project beyond the original period. *If Ethics is in REGIS, do not create this amendment.*
- ❖ **Changing Site Investigators and Administration Contact** notify the RGO of changes to the Site Investigators and Administration Contact
- ❖ **General Amendment** impacting on the type and frequency of services provided by supporting departments at participating sites.
- ❖ **Contract Changes** notify the RGO of changes to contract agreements.

For Ethics approved amendments within REGIS (NSW/ACT), amendments indicated above '*If Ethics is in REGIS, do not create this amendment*' do not need to be created as the RGO will be notified of these amendments within REGIS.

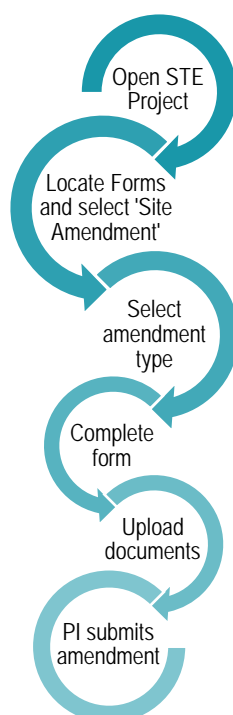
If an ethics approved amendment has been **submitted from another Jurisdiction**, then the ethics documents are mandatory with the submission of the governance amendment.

The following Site Amendments can be submitted to multiple sites at once: Change to CPI, Change to PI and Request for an extension of HREC Approval.

The following Site Amendments require individual submissions: Addition of a Site, General Amendment, Contract Changes and Changing Site Investigators and Administration Contacts.

The following Site amendments do not require Ethics approval: Changing Site Investigators and Administration Contacts and General Amendments.

How does it work in REGIS?



The PI has full access to complete the amendment form and is the only person who can submit. They can give edit and view permissions to others. Editors can complete the application form but cannot submit.

The amendment form can be saved at any time and completed later. A saved amendment form is live for 365 days in the REGIS system.

Form Status

- **In Progress** Form is initially with the applicant for completion and when the form has been reviewed and 'More Information Required' before a decision can be made.
- **Submitted** Form is with the research office.
- **Approved** Form has been reviewed and approved. An email notification will be sent to the PI, Admin Contacts and CPI, as appropriate.

Complete & submit the Site Amendment

Step 1. Locate STE project

If the project is not visible in the 'Top 5 projects' section, select Project to see all.


Tip: Depending on your screen size, you may see either of the above icons

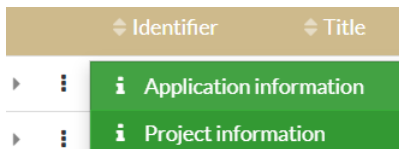


Click the required Project identifier (PID)

Step 2. Select the Site Project

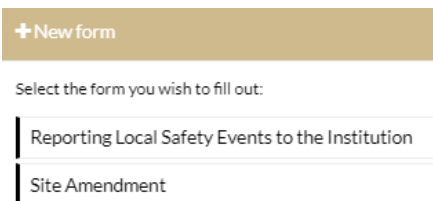
Only an authorised study with no pending milestones can have an amendment created.

Click on the three dots  next to the identifier and then select 'Project information'



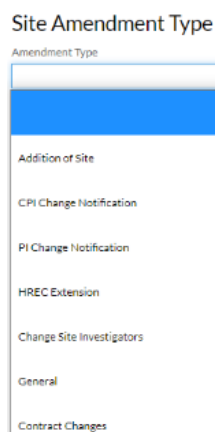
Step 3. Open Amendment Form

Select 'Forms' from the left-hand menu. Click '+New form' and select 'Site Amendment'



Step 4. Complete the amendment form

Choose the type of site amendment from the drop-down menu and complete the form.



Ethics Approved Document Upload

Upload the ethics approved document in this section. If there are **no documents required**, click the document checkbox and select the minus icon to delete the row.

For a General Site Amendment, the 'Related Ethics Amendment Form ID' needs to be selected as it will allow the RGO to complete a more streamlined review.

Related Ethics Amendment Form

Form ID	Form Type
29977	Notification of an amendment to a research study

Uploading a New Document A new document is a document that does not yet physically exist in REGIS.

Note: If you are unsure if the document already exists in REGIS, select 'Yes' and if it does not appear under Document Title then

change the response to 'No' and follow the below instructions.

Upload as New Version: Select 'No'

Document Type: Select from the dropdown

Document Title: Provide a clear and descriptive document description.

Tip: Do not use any character or symbol in the document title that you cannot use in the electronic filename i.e. #%&{}<>?? \$!' += ~" |*

Version and Date: Version and date of the document (normally listed in footer)

Upload File: Will be the uploaded document filename

This information will give the file a REGIS title.

Note: How you name your document in the 'Document Title' section is what the Research Office will see and how it will be listed on the approval notification. See below example;

Document descriptor - your name for the file *

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Click 'Upload New', select 'Choose File' to find your document and then click 'Start Upload'.

To add further new documents, select the plus icon '+' to add more rows.

Uploading a New Version of a Document A new version of an approved document is used when the document is already physically located in REGIS.

If you are uploading an updated version of an approved document, under **Upload as New Version:** Select 'Yes'.

Document Title: Select the form from the dropdown options.

Document Filename: This will preload

Document Type: This will preload

Document Version and Date: Provide the new version and date of the document (normally listed in footer).

Click 'Upload New', select 'Choose File' to find your document and then click 'Start Upload'.

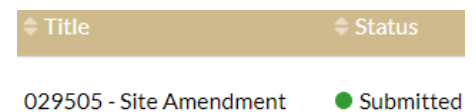
The Document Filename will appear next to the title/descriptor.

To add a tracked version of the document, select the plus icon '+' to add another row and follow the 'Uploading a New Document' instructions.

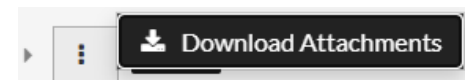
Step 6. Declaration

The PI must submit the amendment. If you are not the PI, save the form and notify the PI once it is ready to submit.

Once submitted, the status of the form will be 'Submitted'. Each amendment form is given a unique identifier number.



To download a copy of the site amendment and attachments, click the three dots next to the site amendment identifier and click 'Download Attachments'.



What Next?

The amendment will be received by the Research Office managing the Site application. Depending on the type of amendment (HREC Extension, Change of CPI and Changing Site Investigators and Administration Contacts), no further action is required.

Once reviewed you will receive either an approval notification or a request for further information (see Governance Amendment – Responding to an Information Request).

For technical assistance, contact
REGIS HELP DESK

support@f1solutions.com.au
1300 073 447